

**UNITED STATES DISTRICT COURT FOR  
THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

*State of Montana v. Abbott Labs., Inc., et al.*,  
D. Mont. Cause No. CV-02-09-H-DWM

**DEFENDANT TAP PHARMACEUTICAL PRODUCTS INC.'S ANSWER AND  
DEFENSES TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

Defendant TAP Pharmaceutical Products Inc. ("TAP") hereby responds to the State of Montana's Second Amended Complaint (the "Complaint") in corresponding numbered paragraphs as follows:

**Preface**

The Complaint improperly and repetitively refers to TAP and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against TAP or other defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to apprise TAP in any meaningful sense of the allegations asserted against it. TAP nevertheless attempts to respond to Plaintiff's allegations to the extent possible under the circumstances. In answering the Complaint, TAP responds only for itself, even when Plaintiff's allegations refer to alleged conduct by TAP and other persons or entities. To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of persons, entities or

defendants other than TAP, TAP is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

The Complaint improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the Complaint are vague or conclusory. The Complaint also includes terms which are undefined and which are susceptible of different meanings.

The Complaint contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine or the joint-defense privilege, TAP reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiffs may have in their possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

TAP specifically denies the existence of, or its participation in, any fraud, fraudulent scheme, conspiracy or enterprise. TAP further denies each and every allegation contained in the Complaint, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations which are contained in any averment or in the Complaint as a whole. Moreover, TAP specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered paragraphs in the Complaint.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

**I.**

1. TAP admits that Plaintiff seeks to bring this action as alleged in Paragraph 1 of the Complaint. TAP denies that Plaintiff is entitled to maintain this action in the manner alleged. TAP denies the remaining allegations in Paragraph 1 of the Complaint.

2. To the extent the allegations in Paragraph 2 of the Complaint refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs establish their contents, and any characterizations thereof are denied. TAP denies the remaining allegations in Paragraph 2 of the Complaint.

3-4. The allegations in Paragraphs 3 and 4 of the Complaint contain Plaintiff's generalizations and self-serving conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 3 and 4 of the Complaint and strict proof is demanded thereof.

5. TAP admits that Congress mandated that Medicare Part B reimbursement be based, in part, in certain circumstances, on AWP and that certain Medicaid programs and private insurance companies reimburse drugs based, in part, in certain circumstances, on AWP. TAP denies the remaining allegations in Paragraph 5 of the Complaint.

6-10. Denied.

11-12. The Court dismissed Plaintiff's "Best Price" claims in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraphs 11 through 12 of the Complaint.

13-17. Denied.

18. TAP admits that Plaintiff purports to bring this action as alleged in Paragraph 18 of the Complaint, but TAP denies that Plaintiff is entitled to maintain this action in the manner alleged.

19-20. Denied.

21. TAP admits that Plaintiff purports to bring this action as alleged in Paragraph 21 of the Complaint, but TAP denies that Plaintiff is entitled to maintain this action in the manner alleged.

22. TAP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of the Complaint and, therefore, denies those allegations.

23. TAP admits that Plaintiff purports to bring this action as alleged in Paragraph 23 of the Complaint, but TAP denies that Plaintiff is entitled to maintain this action in the manner alleged.

## II.

24-28. TAP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 24 through 28 of the Complaint, and, therefore, denies those allegations.

29. Denied.

30. TAP admits that it conducted business in the State of Montana.

31-106. The allegations in Paragraphs 31 through 106 of the Complaint are directed to other defendants and require no response from TAP. To the extent the allegations in Paragraphs 31 through 106 of the Complaint are deemed to include allegations against TAP, they are denied.

107. TAP states that it began as a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd. in 1977. TAP further states that it was incorporated on April 26, 1985. TAP further states that Abbott Laboratories and Takeda American Holdings, Inc., a

wholly owned subsidiary of Takeda Chemical Industries, Ltd., are each 50 percent shareholders of TAP Pharmaceutical Products Inc. TAP denies the remaining allegations in Paragraph 107 of the Complaint.

108. TAP states that, from April 26, 1985 to 1995, TAP was named TAP Pharmaceuticals Inc. In 1995, TAP Pharmaceuticals Inc. became TAP Holdings Inc. In 2000, TAP Holdings Inc. changed its name to TAP Pharmaceutical Products Inc. TAP further states that its headquarters are located in Lake Forest, Illinois. TAP admits that it markets pharmaceutical products for the United States and Canada. TAP denies the remaining allegations in Paragraph 108 of the Complaint.

109. Denied.

110-111. The allegations in Paragraphs 110 through 111 of the Complaint are directed to other defendants and require no response from TAP. To the extent the allegations in Paragraphs 110 through 111 of the Complaint are deemed to include allegations against TAP, they are denied.

### **III.**

112. The allegations in Paragraph 112 of the Complaint contain Plaintiff's generalizations and self-serving conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraph 112 of the Complaint and strict proof is demanded thereof.

113-122. TAP states that the publications cited in Paragraphs 113 through 122 of the Complaint establish their contents. TAP denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to TAP. TAP is without knowledge or information sufficient to form a belief as to the truth of the

remaining allegations in Paragraphs 113 through 122 of the Complaint, and, therefore, denies those allegations.

123. Denied.

#### IV.

124-141. The allegations in Paragraphs 124 through 141 of the Complaint contain Plaintiff's generalizations and self-serving conclusions regarding the Prescription Drug Market without specific detailed factual allegations averred against TAP, and thus no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 124 through 141 of the Complaint and strict proof is demanded thereof. Moreover, TAP states that the publication cited in Paragraphs 124 through 141 of the Complaint establishes its content. TAP denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to TAP.

#### V.

142-145. Paragraphs 142 through 145 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP states that the statute and document cited in Paragraphs 142 through 145 of the Complaint establish their contents, and denies that Plaintiff has accurately characterized any conclusions that may be drawn from that document and statute. TAP denies the remaining allegations in Paragraphs 142 through 145 of the Complaint.

146. TAP admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth, in part, at 42 C.F.R. 405.517. To the extent that Plaintiff purports to summarize or characterize 42 C.F.R. 405.517, Paragraph 146 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraph 146 of the Complaint.

147. Paragraph 147 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, TAP admits that federal statutes and regulations set forth the payment methodology for drugs under Medicare Part B. TAP is without knowledge or information sufficient to form a belief as to the accuracy of the unattributed quotations in Paragraph 147 of the Complaint. TAP denies the remaining allegations in Paragraph 147 of the Complaint.

148. TAP admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth, in part, at 42 C.F.R. 405.517. To the extent that Plaintiff purports to summarize or characterize 42 C.F.R. 405.417, Paragraph 148 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraph 148 of the Complaint.

149-150. Paragraphs 149 and 150 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP states that Program Memorandum AB-99-63 establishes its content, and denies that Plaintiff has accurately characterized any conclusion that may be drawn from it. TAP denies the remaining allegations in Paragraphs 149 and 150 of the Complaint.

151. TAP admits that there are no government regulations describing how AWP's are calculated, nor any other statutory or regulatory definitions or descriptions of AWP's. TAP admits that it reports certain pricing information for its medicines to independently produced pricing publications. TAP denies the remaining allegations in Paragraph 151 of the Complaint.

152. Paragraph 152 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, TAP admits that federal law governs the manner in which Medicare Part B reimburses medical providers for certain drugs. TAP is

without knowledge or information sufficient to form a belief as to whether the summary of those laws set forth in Paragraph 152 of the Complaint is accurate in all instances. TAP denies the remaining allegations in Paragraph 152 of the Complaint.

153. Admitted.

154-157. TAP states that the publications cited in Paragraphs 154 through 157 of the Complaint establish their contents. TAP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraphs 154 through 157 of the Complaint, and, therefore, denies those allegations.

158. Paragraph 158 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, TAP admits that federal and state law govern the manner in which certain low income individuals may be covered by both Medicare and Medicaid. TAP is without knowledge or information sufficient to form a belief as to whether the summary of those laws set forth in Paragraph 158 of the Complaint is accurate in all instances. TAP denies the remaining allegations in Paragraph 158 of the Complaint.

159. Paragraph 159 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, TAP states that 42 C.F.R. 440.120 establishes its content. TAP is without knowledge or information sufficient to form a belief as to remaining allegations in Paragraph 159 of the Complaint and, therefore, denies those allegations.

160. TAP states that the publication cited in Paragraph 160 of the Complaint establishes its content. TAP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 160 of the Complaint, and, therefore, denies those allegations.



161. TAP states that the publication cited in Paragraph 161 of the Complaint establishes its content. TAP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 161 of the Complaint, and, therefore, denies those allegations.

162. Paragraph 162 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, TAP states that the regulations and document cited in Paragraph 162 of the Complaint establish their contents, and denies that Plaintiffs have accurately characterized any conclusions that may be drawn from those regulations and document. TAP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 162 of the Complaint, and therefore denies those allegations.

163. TAP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 163 of the Complaint and, therefore, denies those allegations.

## **VI.**

164. Denied.

165. TAP is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 165 of the Complaint and, therefore, denies those allegations. TAP admits the second sentence of Paragraph 165 of the Complaint. TAP denies the third sentence of Paragraph 165 of the Complaint.

166. TAP is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 166 of the Complaint and, therefore, denies those allegations. TAP denies the remaining allegations in Paragraph 166 of the Complaint.

167. TAP admits that certain pharmaceutical compendia publish certain pricing information. TAP denies the remaining allegations in Paragraph 167 of the Complaint.

168. TAP states the documents cited in Paragraph 168 of the Complaint establish their contents. TAP denies that Plaintiff has accurately characterized the findings, opinions, statements or conclusions stated in those documents, or that such are applicable to TAP. TAP denies the remaining allegations in Paragraph 168 of the Complaint.

169. Denied.

170-171. TAP states that the April 2003 OIG report cited in Paragraphs 170 and 171 of the Complaint establishes its content. TAP denies that Plaintiff has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to TAP. TAP denies the remaining allegations in Paragraphs 170 and 171 of the Complaint.

172. Denied.

## **VII.**

173-175. Denied.

176. TAP admits that at certain times it reported pricing information to various pharmaceutical compendia. TAP denies the remaining allegations in Paragraph 176 of the Complaint.

177-178. Denied.

179. TAP admits that at certain times it reported pricing information to various pharmaceutical compendia. TAP denies the remaining allegations in Paragraph 179 of the Complaint.

180-184. Denied.

185-200. The allegations in Paragraphs 185 through 200 of the Complaint are directed to other defendants and require no response from TAP. To the extent the allegations in

Paragraphs 185 through 200 of the Complaint are deemed to include allegations against TAP, they are denied.

201-209. Denied.

210. TAP admits that certain federal and state agencies have investigated marketing and pricing practices with respect to certain Medicare and Medicaid reimbursable products. TAP denies the remaining allegations in Paragraph 210 of the Complaint.

211-212. TAP states that the September 28, 2002, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 211 and 212 of the Complaint establishes its content. TAP denies that Plaintiff has accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to TAP. TAP denies the remaining allegations in Paragraphs 211 and 212 of the Complaint.

213. TAP admits that it has not been advised that the government investigations have been closed as the date of the answer. TAP denies the remaining allegations in Paragraph 213 of the Complaint.

214. Denied.

215. TAP admits that Plaintiff purports to seek relief for the drugs set forth in Appendix A and identified in Paragraph 215 of the Complaint. TAP denies that Plaintiff is entitled to the relief sought in Paragraph 215 of the Complaint. TAP denies the remaining allegations in Paragraph 215 of the Complaint.

216-567. The allegations in Paragraphs 216 through 567 of the Complaint are directed to other defendants and require no response from TAP. To the extent the allegations in

Paragraphs 216 through 567 of the Complaint are deemed to include allegations against TAP, they are denied.

568. Denied.

569. TAP admits that Plaintiff purports to bring this action as alleged in Paragraph 569 of the Complaint, but TAP denies that Plaintiff is entitled to maintain this action in the manner alleged or that Plaintiff is entitled to any relief. TAP denies the remaining allegations in Paragraph 569 of the Complaint.

570-571. Denied.

572. TAP responds that, in this paragraph, Plaintiff purports to summarize the allegations contained in certain Criminal Informations and an Indictment. TAP states that the Indictment that Plaintiff purports to summarize has been superseded. TAP refers to the superseding Indictment and Criminal Informations for accurate statements of their contents. TAP denies the remaining allegations in Paragraph 572 of the Complaint.

573. TAP admits that certain of TAP's employees would at times conduct meetings regarding Lupron® with certain physicians referred to as "Business Reviews." TAP denies the remaining allegations in Paragraph 573 of the Complaint.

574. TAP admits that certain of TAP's employees created certain documents and other materials which compared the math calculation of prices of Lupron® and Zoladex® and showed such materials to certain physicians. TAP denies the remaining allegations in Paragraph 574 of the Complaint.

575-576. Denied.

577. TAP admits that, on or about October 3, 2001, TAP Pharmaceutical Products Inc. agreed to plead guilty to a one-count Information for conspiracy under 18 U.S.C. §371 to

violate the Prescription Drug Marketing Act by providing Lupron® samples to certain physicians knowing that they would seek reimbursement for them. TAP further admits that TAP issued a press release on October 3, 2001 discussing the guilty plea agreement entered into with the United States Department of Justice regarding Lupron®. TAP refers to the October 3, 2001 press release for an accurate statement of its content. TAP denies the remaining allegations in Paragraph 577 of the Complaint.

578. Denied.

579. TAP states that the Indictment to which the Plaintiffs purport to refer in this paragraph has been superseded. TAP refers to the Superseding Indictment for an accurate statement of its content. TAP admits that a TAP employee offered Tufts educational grants. TAP denies the remaining allegations in Paragraph 518 of the Complaint.

580-581. Denied.

582. TAP admits that the United States Attorney's Office for the District of Massachusetts participated in an investigation of TAP with regard to the sale and marketing of Lupron®. TAP denies the remaining allegations in Paragraph 582 of the Complaint.

583. TAP admits that, on or about October 3, 2001, TAP Pharmaceutical Products Inc. agreed to plead guilty to a one-count Information for conspiracy under 18 U.S.C. §371 to violate the Prescription Drug Marketing Act by providing Lupron® samples to certain physicians knowing that they would seek reimbursement for them and to pay a \$290 million criminal fine. TAP further admits that representatives of the United States Department of Justice have stated that the \$290 million paid by TAP is the largest criminal fine in a U.S. health care fraud prosecution. TAP further admits that TAP entered into a civil settlement agreement with the United States government regarding Lupron® in which TAP agreed to pay approximately \$559.5

million to the United States, without any finding or admission of wrongdoing. TAP further admits that TAP entered into a civil settlement agreement with the fifty states and the District of Columbia regarding Lupron® in which TAP agreed to pay approximately \$25.5 million, without any finding or admission of wrongdoing. TAP further admits that TAP entered into a Corporate Integrity Agreement with the government, and refers to the Agreement for an accurate statement of its content. TAP further admits that on or about October 3, 2001, the United States Attorneys' Office in Boston made an announcement about TAP's Plea Agreement and Civil Settlement. TAP further admits that certain current or former TAP employees and urologist Dr. John Romano were indicted. TAP avers that of the six current or former TAP employees that were indicted, five have been acquitted of all charges and the guilty plea of the remaining one is currently under review by the court. TAP refers to the referenced Plea Agreement, Civil Settlement, Corporate Integrity Agreement, Side Letters and Indictment for accurate statements of their contents. TAP denies the remaining allegations in Paragraph 583 of the Complaint.

584. TAP states that the December 6, 2001 Hearing Transcript cited in Paragraph 584 of the Complaint establishes its content. TAP denies the remaining allegations in Paragraph 584 of the Complaint.

585. Denied.

586. To the extent that the allegations in Paragraph 586 of the Complaint constitute legal conclusions, no response is required. TAP refers to the Indictment, which has been superseded, for an accurate statement of its content. TAP further states that Mr. MacKenzie has been acquitted of all charges. TAP denies the remaining allegations in Paragraph 586 of the Complaint.

587. TAP admits that Paragraph 587 of the Complaint contains an excerpt from a document produced in MDL 1430. TAP denies the remaining allegations in Paragraph 587 of the Complaint. TAP further states that Mr. MacKenzie has been acquitted of all charges

588. TAP admits that a presentation created by one of TAP's employees included the language quoted in Paragraph 588 of the Complaint. TAP denies the remaining allegations in Paragraph 588 of the Complaint. TAP further states that Mr. MacKenzie has been acquitted of all charges

589-602. The allegations in Paragraphs 589 through 602 of the Complaint are directed to another defendant and require no response from TAP. To the extent allegations in Paragraphs 589 through 602 of the Complaint are deemed to include allegations against TAP, they are denied.

#### **VIII.**

603-634. The Court dismissed Plaintiff's "Best Price" claims in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraphs 603 through 634 of the Complaint.

#### **IX.**

635. Denied.

636. TAP states that the 2003 CMS document cited in Paragraph 636 of the AMCC establishes its content. TAP denies that Plaintiff has accurately characterized any alleged CMS finding, opinion, statement or conclusion. TAP admits that it sells its pharmaceuticals in a competitive market and, as such, takes steps to keep certain information relating to its pharmaceuticals confidential. TAP denies the remaining allegations in Paragraph 636 of the Complaint.

637-641. Denied.

642-643. The allegations in Paragraphs 642 and 643 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 642 and 643 of the Complaint.

**X.**

644. TAP denies that patients have suffered damages or injuries as alleged in Paragraph 644 of the Complaint. TAP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 644 of the Complaint.

645. Denied.

646-648. The allegations in Paragraphs 646 through 648 of the Complaint are directed to other defendants and require no response from TAP. To the extent the allegations in Paragraphs 646 through 648 of the Complaint are deemed to include allegations against TAP, they are denied.

649. TAP is without information knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 649 of the Complaint. TAP denies the remaining allegations in Paragraph 649 of the Complaint.

650. Denied.

651. The Court dismissed Plaintiff's "Best Price" claims in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraph 651 of the Complaint.

652-653. Denied.

**XI.**

**COUNT I**

654. TAP realleges and incorporates by reference its responses to Paragraphs 1 through 653 of the Complaint.



655. TAP admits that Plaintiff purports to bring this action and to seek relief under Count I of the Complaint as alleged in Paragraph 655, but TAP denies that Plaintiff is entitled to maintain this action as alleged or to any relief against TAP under Count I. TAP further denies the remaining allegations in Paragraph 655 of the Complaint.

656-660. The allegations in Paragraphs 656 through 660 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 656 through 660 of the Complaint.

## **COUNT II**

661. TAP realleges and incorporates by reference its responses to Paragraphs 1 through 660 of the Complaint.

662. To the extent the allegations in Paragraph 662 of the Complaint refer to Plaintiff's "Best Price" claims dismissed in the Court's Order dated June 10, 2004, TAP does not respond to Paragraph 662. TAP admits that Plaintiff purports to bring this action and to seek relief under Count II of the Complaint as alleged in Paragraph 662, but TAP denies that Plaintiff is entitled to maintain this action as alleged or to any relief against TAP under Count II. TAP denies the remaining allegations in Paragraph 662 of the Complaint.

663-667. To the extent the allegations in Paragraph 663 through 667 of the Complaint refer to Plaintiff's "Best Price" claims dismissed in the Court's Order dated June 10, 2004, TAP does not respond to Paragraphs 663 through 667. Additionally, the allegations in Paragraphs 663 through 667 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraphs 663 through 667 of the Complaint.

**COUNT III**

668-679. The Court dismissed Count III in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraphs 668 through 679 of the Complaint.

**COUNT IV**

680-691. The Court dismissed Count IV in its Order dated June 10, 2004. Accordingly, TAP does not respond to Paragraphs 680 through 691 of the Complaint.

**COUNT V**

692. TAP realleges and incorporates by reference its responses to Paragraphs 1 through 691 of the Complaint.

693. The allegations in Paragraph 693 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, TAP denies the allegations in Paragraph 693 of the Complaint.

**UNNUMBERED “WHEREFORE” PARAGRAPHS AND REQUEST FOR JURY TRIAL**

TAP denies Plaintiff is entitled to a judgment or any other relief requested in their unnumbered “WHEREFORE” Paragraphs following each count in the Complaint or the unnumbered Paragraph following Paragraph 693 of the Complaint.

Listed below, TAP has provided a list of defenses without assuming any burden of proof:

**FIRST DEFENSE**

Plaintiff fails to state a claim against TAP upon which relief may be granted.

**SECOND DEFENSE**

Some or all of Plaintiff’s claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**THIRD DEFENSE**

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of TAP as alleged in the Complaint.

**FOURTH DEFENSE**

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against TAP based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

**FIFTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana.

**SIXTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

**SEVENTH DEFENSE**

Any and all actions taken by TAP with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**EIGHTH DEFENSE**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**NINTH DEFENSE**

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

**TENTH DEFENSE**

Plaintiff's claims against TAP are barred because TAP has complied with all applicable regulations of the federal and state governments.

**ELEVENTH DEFENSE**

Plaintiff's claims against TAP are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**TWELFTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because they violate TAP's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**THIRTEENTH DEFENSE**

TAP's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

**FOURTEENTH DEFENSE**

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multiple-source medicine allegations against TAP contained in the Complaint.

**FIFTEENTH DEFENSE**

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited to, Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

**SIXTEENTH DEFENSE**

Plaintiff fails to allege with particularity its civil conspiracy claims against TAP as required by FED. R. CIV. P. 9(b).

**SEVENTEENTH DEFENSE**

Plaintiff's claims against TAP are barred because TAP did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

**EIGHTEENTH DEFENSE**

Plaintiff's claims against TAP are barred, in whole or in part, because TAP did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against TAP that Plaintiff alleges to be false or misleading, TAP had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**NINETEENTH DEFENSE**

Plaintiff's claims against TAP are barred because TAP did not directly or indirectly engage in any conduct in violation of state or federal law.

**TWENTIETH DEFENSE**

TAP denies that Plaintiff has valid consumer protection claims against TAP under Montana state law. However, if such claims are found to exist, TAP pleads all available defenses under the applicable laws.

**TWENTY-FIRST DEFENSE**

Any allegedly fraudulent statements or conduct of TAP did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Montana.

**TWENTY-SECOND DEFENSE**

TAP's conduct was not "deceptive" as required under Montana consumer protection laws.

**TWENTY-THIRD DEFENSE**

To the extent that Plaintiff seeks equitable relief against TAP, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

**TWENTY-FOURTH DEFENSE**

Plaintiff did not rely on the allegedly fraudulent statements or conduct of TAP as required under the Montana consumer protection laws.

**TWENTY-FIFTH DEFENSE**

Any allegedly fraudulent statement or conduct of TAP was not consumer-oriented as required under the Montana consumer protection laws.

**TWENTY-SIXTH DEFENSE**

Plaintiff's claims against TAP for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**TWENTY-SEVENTH DEFENSE**

Some or all of Plaintiff's claims for injunctive relief against TAP are barred by the doctrines of *in pari delicto* and/or unclean hands.

**TWENTY-EIGHTH DEFENSE**

Some or all of Plaintiff's claims against TAP arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**TWENTY-NINTH DEFENSE**

Plaintiff's claims against TAP are barred, in whole or in part, due to its failure to join indispensable parties.

**THIRTIETH DEFENSE**

Plaintiff's claims against TAP are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

**THIRTY-FIRST DEFENSE**

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

**THIRTY-SECOND DEFENSE**

Plaintiff's claims against TAP for damages are barred, in whole or in part, because:

(1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to TAP; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by TAP after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**THIRTY-THIRD DEFENSE**

TAP is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**THIRTY-FOURTH DEFENSE**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from TAP.

**THIRTY-FIFTH DEFENSE**

Plaintiff fails to allege facts or a cause of action against TAP sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

**THIRTY-SIXTH DEFENSE**

Plaintiff's punitive damages claims against TAP: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against TAP; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give TAP prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of TAP's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Montana; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate TAP's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Montana; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent



judgments against TAP for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of TAP's medicines, would constitute impermissible multiple punishments for the same wrong in violation of TAP's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Montana; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate TAP's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according TAP the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate TAP's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana.

### **THIRTY-SEVENTH DEFENSE**

Plaintiff's claim for punitive damages against TAP cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly

prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of TAP; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate TAP's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Montana.

#### **THIRTY-EIGHTH DEFENSE**

Plaintiff's claim for punitive damages against TAP cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate TAP's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate TAP's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Montana.

#### **THIRTY-NINTH DEFENSE**

Plaintiff is barred from seeking damages after the date on which TAP and Montana entered into a settlement agreement relating to Lupron®, because, as a result of that settlement, Plaintiff received Average Sales Price data for TAP's drugs.

**FORTIETH DEFENSE**

TAP adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein.

**FORTY-FIRST DEFENSE**

TAP hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, TAP prays that this Court:

1. Dismiss the State of Montana's Second Amended Complaint with prejudice and enter judgment in favor of TAP and against plaintiffs;
2. Award TAP its costs and expenses; and
3. Grant such other and further relief for TAP as this Court deems just and proper.

Respectfully Submitted,

Dated: July 19, 2004

A handwritten signature in cursive script, reading "Lee Ann Russo", written over a horizontal line.

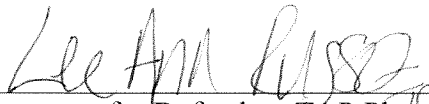
Joseph F. Savage (BBO# 443030)  
TESTA HURWITZ & THIBEAULT LLP  
125 High Street  
Boston, Massachusetts 02110-2704  
Telephone: (617) 248-7000  
Facsimile: (617) 790-0297

Daniel E. Reidy  
Lee Ann Russo  
Tina M. Tabacchi  
JONES DAY  
77 West Wacker Drive  
Chicago, Illinois 60601  
Telephone: (312) 782-3939  
Facsimile: (312) 782-8585

***Counsel for Defendant TAP Pharmaceutical  
Products Inc.***

**CERTIFICATE OF SERVICE**

I hereby certify that on this 19th day of July, 2004, a true and correct copy of DEFENDANT TAP PHARMACEUTICAL PRODUCTS INC.'S ANSWER AND DEFENSES TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

  
\_\_\_\_\_  
Attorney for Defendant TAP Pharmaceutical  
Products Inc.